REMARKS/ARGUMENTS

This is in response to the Office Action mailed August 19, 2003, in the above-referenced application.

Claim 4 is rejected under 35 USC § 112, second paragraph, as indefinite. Applicants respectfully submit that the objected to language is proper. The Markush group members are selected from polypeptides defined in Claim 1 to include at least one arginine residue. See the last line of Claim 1. However, Claim 4 is amended to move the phrase "comprising at least one arginine residue" from the end of Claim 4 to after reference to a filaggrin variant. The amendment to Claim 4 merely restates what was previously recited in Claim 4, and accordingly does not affect the scope of protection afforded Applicants, including any protection available under the doctrine of equivalents.

Claims 1-6 are rejected under 35 USC § 102(b) as anticipated by Simon et al. The Office argues that Claim 1 includes "heterologous peptides in a broad interpretation of the Claim 1 language." Accordingly, the Office concludes that Claim 1 "does not exclude a heterologous peptide." Applicants respectfully traverse this rejection.

The Office's attention is directed to the transition phrase "which consists of" in Claim 1. The term "which consists of" of Claim 1 is amended to recite "consisting of" This amendment merely restates the transition phrase in a form more familiar under U.S. practice.

The transitional phrase "consisting of" excludes any element not specified in the claim. Thus, in this case, heterologous peptides are excluded from the claimed invention. See MPEP Section 2111.03.

As Applicants have previously noted, naturally occurring human filaggrin does not consist of a single polypeptide. Rather, naturally occurring human filaggrin includes a population of polypeptides of different sequences since it is synthesized as a large precursor (profilaggrin) including filaggrin units displaying important variations between them. In contrast, when a recombinant or synthetic filaggrin or filaggrin fragment is prepared, it is obtained from the sequence of an individual filaggrin unit. This results in a population of polypeptides having the same sequence.

The artificial antigen of Claim 1 is derived from a single filaggrin unit. As noted above, Claim 1 recites an artificial antigen that consists of a recombinant or synthetic polypeptide

derived from any one of the filaggrin variants represented by SEQ ID NO: 7. As a result, the claimed invention is a homogenous preparation of polypeptides having the same sequence and does not include a mixture of polypeptides of different sequences.

In contrast, Simon et al. refers to a citrulline-containing epitope present only on the "post-translationally modified filaggrin." Page 436, column 2, first paragraph cited by the Examiner. This corresponds to filaggrin purified from human epidermis, as discussed in the first paragraph in the "Materials and Methods" section of the article.

This preparation is used in the immunoblotting of Figures 3 and 4. Figure 4 illustrates that the preparation displays the comma-shaped migration typical of filaggrin extracted from human epidermis. This in turn reflects the heterogeneity of such a preparation, in contrast to the homogenous nature of the claimed invention.

Page 434, column 2, second paragraph of Simon et al. is directed to an alternative preparation. Here, Simon et al. refer to synthetic peptides derived from the consensus sequence of human filaggrin. These peptides represent fragments of the "native" i.e., not post translationally modified, sequence of filaggrin. These peptides are not citrullinated. Further, Simon et al. nowhere teach or suggest treating the synthetic peptides to citrullinate the same.

In summary, Simon et al. discuss either peptides derived from human epidermis that are not homogenous or synthetic peptides that are not citrullinated. Simon et al do not teach or suggest synthetic peptides recited in Claim 1 which are homogenous (derived from one of the filaggrin variants of SEQ ID NO: 7) and also citrullinated. Further, Simon et al. do not suggest or motivate one skilled in the art to modify the peptides taught therein to provide the claimed invention. Accordingly, Applicants respectfully submit that the claimed invention is patentable and request withdrawal of this rejection.

The rejections of record having been addressed in full in the foregoing, it is respectfully submitted that this application is now in condition for allowance, which action is respectfully requested. Should the Examiner have any questions regarding the foregoing, it is respectfully requested that she contact the undersigned at her convenience to expedite allowance of this matter.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper.

However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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I hereby certify that this paper is being facsimile transmitted to the U. S. Patent and Trademark Office at Fax No (703) 872-9306 on the date shown below.

Grace R. Rippy

January 20, 2004
Date